

## REMARKS/ARGUMENTS

Claims 8-13 are pending herein. Claims 1-7 have been cancelled hereby in favor of new claims 8-13. Applicant respectfully submits that the new claims are supported by the original specification and claims, and that no new matter has been added.

1. The §102(b) rejection of claims 1, 4, 6 and 7 over Ying's Quick Chocolate Almond Mouse Recipe is noted, but deemed moot in view of the cancellation of those claims and in view of the new claims submitted above. Accordingly, Applicant respectfully requests that the above rejection be reconsidered and withdrawn.
2. The §102(b) rejection of claims 1, 3, 4 and 7 over Ying's Rice Pudding Recipe is noted, but deemed moot in view of the cancellation of those claims and in view of the new claims submitted above. Accordingly, Applicant respectfully requests that the above rejection be reconsidered and withdrawn.
3. The §103(a) rejection of claims 1-4 and 7 over Ying's Rice Pudding Recipe in view of Kabushiki is noted, but deemed moot in view of the new claims submitted above. Accordingly, Applicant respectfully requests that the above rejection be reconsidered and withdrawn.
4. Claims 1 and 5 were rejected under §103(a) over Carlsson. This rejection is moot in view of the cancellation of claims 1 and 5. To the extent that the PTO might attempt to assert this rejection against the new claims 8-12 submitted above, it is respectfully traversed.

Independent claim 8 recites an enteral nutrition product for enteral administration, not orally, but directly to a stomach or intestines of a dysphagic patient from an external container connected to an external portion of a feeding tube provided through a through-hole of a stoma formed through a portion of the abdominal and stomach walls of the patient upon the application of pressure to said external

container. The enteral nutrition product comprises a semi-solid material having a substantially self-supporting consistency that deforms to flow under an externally applied load without liquefying and that is capable of containing a higher concentration of a nutrient component than a liquid. The semi-solid material comprises a mixture of a liquid nutrient solution and a semi-solidifying agent comprising agar that is added to the liquid nutrient solution. The mixture comprises the semi-solidifying agent and the liquid nutrient solution in a predetermined ratio that is sufficient to ensure that the self-supporting consistency of the semi-solid enteral nutrition product remains substantially unchanged before, during, and after enteral administration of the semi-solid enteral nutrition product into the patient. The self-supporting consistency of the semi-solid enteral nutrition product is further maintained within the stomach or the intestines of the patient such that the semi-solid enteral nutrition product does not liquefy due to the body temperature of the patient, to thereby prevent the patient from experiencing gastro-esophageal reflux.

Claim 12 depends from independent claim 8 and recites that the semi-solidifying agent comprising agar is added in amount of 1 gram to 200 ml of a diluting liquid that is added to the liquid nutrient solution.

The inventor discovered that, for administration of enteral nutrition products to dysphagic patients via a feeding tube, it is ideal for the enteral nutrition products to be lower in calories, and to run though the feeding tube without leaving residual product and without any need to later flush feeding tube. As stated in paragraph [0124] on page 33 of the substitute specification filed on January 24, 2005, agar is lower in calories and is also less adhesive or sticky which enables the enteral nutrition product according to the present invention to run through the feeding tube without leaving residual product in/on the tube and without any need to later flush the feeding tube.

Agar is the best selection for the semi-solidifying agent according to the present invention with respect to providing improved health and nutrition for the patient recipients and with respect to reducing the efforts of nurses, caregivers or helpers.

Applicant respectfully submits, however, that none of the applied references expressly, suggestively or inherently teach the use of agar as a semi-solidifying agent used in any type of reflux-free enteral nutrition products.

The PTO asserted that Carlsson “establishes the knowledge in the art using agar as a thickening agent, in enteral emulsions” (Office Action, page 6, lines 17-19), but admitted that Carlsson fails to disclose or suggest the specifically claimed amount of agar relative to the diluting liquid. The PTO also admitted that Carlsson fails to disclose or suggest the various specific concentrations of active ingredients recited in the pending claims. Even in view of these admitted deficiencies, however, the PTO asserted that it would have been obvious to “follow the suggestions of the ‘639 patent in order to provide a stable enteral formulation that can also act as a carrier for pharmaceutical agents,” and that “a stable enteral formulation capable of provided delivery of pharmaceutical agents would be expected” (Office Action, page 7, lines 14-16).

Applicant respectfully submits, however, that while Carlsson may teach that agar could be used as a thickening agent for biological applications, Carlsson does not even begin to disclose or suggest that the claimed consistency characteristics of the resultant formulations should desirably or even could possibly be achieved. Moreover, the claimed consistency characteristics are not recognized or relevant to Carlsson, since Carlsson does not in any way relate to the prevention of reflux in patients fed enterally via direct administration to the stomach or intestines. To the contrary, the claimed product does not flow in the manner intended in Carlsson and as such, would not be desirable as a vehicle to deliver nutrients or pharmaceutical products as Carlsson intends.

The experimental results presented in the present specification demonstrate the unexpected nature and criticality associated with the specifically claimed ratios, concentrations and compositions according to the present invention. Such unexpected results establish the non-obviousness of the present invention and must be considered by the PTO. In that regard, please refer to the Amendment filed on May 11, 2006, the entire remarks of which are incorporated herein.

Indeed, Applicant respectfully submit that one skilled in the art would not have had any reasonable expectation that Carlsson's formulation could possibly exhibit the claimed characteristics, which, again, are not relevant or desirable to Carlsson. Furthermore, such skilled artisans would not have had any logical reason to try to modify Carlsson to try to achieve such otherwise undisclosed characteristics and unexpected results. To suggest otherwise is not only illogical, but indicative of an improper application of hindsight-based analysis used by the PTO merely in an attempt to continue to reject otherwise patentable claims.

Applicant respectfully submits that all claims pending herein define patentable subject matter over Carlsson for at least the reasons explained above. In addition, however, Applicant respectfully submits that evidence of the secondary considerations, which the PTO must consider is included in the Rule 132 Declaration filed herewith. The Declaration establishes that the present invention has been recognized as novel and non-obvious and has been patented in Japan. The Japanese patent corresponding to the present invention has been licensed for commercial purposes, and its commercial viability is further verified to by the ongoing negotiations to establish additional licenses. The importance, novelty and non-obviousness of the present invention has also been recognized and praised by Applicant's peers in numerous publications. These publications along with the Japanese patent and the license(s) therefore also demonstrate that the present invention solves a long-felt but heretofore unresolved need.

Applicants respectfully submit that the PTO must properly consider such secondary considerations, and that the evidence of secondary considerations presented herein is sufficient to rebut the PTO's *prima facie* case of obviousness against the present invention defined in the pending claims.

For at least the foregoing reasons, Applicant respectfully requests that the above rejection be reconsidered and withdrawn.

If the Examiner believes that contact with Applicant's attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicant's attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,

April 15, 2008

\_\_\_\_\_  
Date



Stephen P. Burr  
Reg. No. 32,970

Nicole J. Buckner  
Reg. No. 51,508

SPB/NB/cmb  
BURR & BROWN  
P.O. Box 7068  
Syracuse, NY 13261-7068

Customer No.: 025191  
Telephone: (315) 233-8300  
Facsimile: (315) 233-8320